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10/565,021	08/29/2006	Richard Schlegel	GUH-P01-007	9002

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EXAMINER
AEDER, SEAN E

ART UNIT	PAPER NUMBER
1642	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/565,021	SCHLEGEL, RICHARD	
	Examiner	Art Unit	
	Sean E. Aeder	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,17,25-29,31,38,46,53 and 60-72* is/are pending in the application.

4a) Of the above claim(s) *2,3,6-8,25-29,31,38,46,53,61,62 and 65-67* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4, 5, 17, 60, 63, 64, and 68-72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/21/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Election/Restrictions

The response filed on 6/8/07 to the restriction requirement of 3/6/07 has been received. Applicant has elected Group 1 and the species transferrin receptor and beta-catenin for examination with traverse. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the restriction is maintained (MPEP 818.03(a).

Further, the Response of 6/8/07 inquired why claims 9-16 were not included in any of he nine groups set forth in the restriction requirement of 3/6/07 and requested that claims 9-16 be examined with the elected group. In reply, the Examiner would like to point-out that claims 9-16 were not included in any of he nine groups set forth in the restriction requirement of 3/6/07 because Applicant cancelled claims 9-16 on 1/17/06. Further, the Response of 6/8/07 indicates that claims 9-16 remain cancelled. The examiner finds no reason to restrict or examine cancelled claims.

Claims 1-8, 17, 25-29, 31, 38, 46, 53, and 60-72 are pending.

Claims 2, 3, 6-8, 25-29, 31, 38, 46, 53, 61, 62, and 65-67 are withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to a non-elected invention.

Claims 1, 4, 5, 17, 60, 63, 64, and 68-72 are currently under consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 17, 60, 63, 64, and 68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected for being incomplete for omitting essential steps, such omission amounting to a gap between the steps. Claim 1 recites a method of diagnosing or aiding in the diagnosis of cervical cancer in a female comprising analyzing the status of at least two biomarkers; however, claim 1 does not indicate what particular status indicates that a female has a particular diagnosis or what particular status would aid in what particular way to diagnosing a female with cervical cancer. Thus, there are missing steps involving correlating the status of biomarkers with a diagnosis. See MPEP § 2172.01.

Claim 17 is rejected for omitting essential steps, such omission amounting to a gap between the steps. Claim 17 recites a method of detecting immortalization of cervical cells in a female comprising analyzing the status of at least two biomarkers; however, claim 17 does not indicate what particular status would indicate that a female has immortalized cervical cells. Thus, there is a missing step involving correlating a particular status with immortalized cervical cells. See MPEP § 2172.01.

Claim 60 and dependent claims 63, 64, and 68 are rejected for being incomplete for omitting essential steps, such omission amounting to a gap between the steps. Claim 60 recites a method of classifying the grade of a cervical lesion comprising determining the status of at least two biomarkers; however, the claims do not indicate what particular status would indicate that a cervical lesion is a particular grade. Thus, there is a missing step involving correlating a status to a particular grade. See MPEP § 2172.01.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 69-72 are rejected under 35 U.S.C. 102(b) as being anticipated by Orntoft (US Patent 6,335,170 B1; 1/1/02).

Orntoft et al teaches a kit comprising control reagents, nucleic acids, and antibodies for detecting the status of transferrin receptor and beta-catenin (see Examples 7 and 8, in particular). Further, it is noted that claims 69-72 appear to contain

statements reciting purpose or intended use. It is noted that statements of intended purposes or uses are not considered limitations because they merely state an intended use of the invention rather than any distinct definition of any of the claimed invention's limitations (see Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999)). Thus, recitation of statements describing the claimed product as a product which is intended to be used to diagnose or aid in the diagnosis of cervical cancer are not given patentable weight and are not limitations to the claims.

Claims 69, 70, and 72 are rejected under 35 U.S.C. 102(e) as being anticipated by Rokutan et al (US 2003/0059791 A1; filed 2/27/02).

Rokutan et al teaches a kit comprising control reagents and nucleic acids for detecting the status of transferrin receptor and beta-catenin (see paragraph 116, in particular). Further, it is noted that claims 69, 70, and 72 appear to contain statements reciting purpose or intended use. As stated above, statements of intended purposes or uses are not considered limitations because they merely state an intended use of the invention rather than any distinct definition of any of the claimed invention's limitations (see Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999)). Thus, recitation of statements describing the claimed product as a product which is intended to be used to diagnose or aid in the diagnosis of cervical cancer are not given patentable weight and are not limitations to the claims.

Claims 69-72 are rejected under 35 U.S.C. 102(e) as being anticipated by Mack and Markowitz (US 2003/0235820 A1; filed 2/27/02)

Mack and Markowitz teaches a kit comprising control reagents, nucleic acids, and antibodies for detecting the status of transferrin receptor and beta-catenin (see paragraphs 324-326, in particular). Further, it is noted that claims 69-72 appear to contain statements reciting purpose or intended use. As stated above, statements of intended purposes or uses are not considered limitations because they merely state an intended use of the invention rather than any distinct definition of any of the claimed invention's limitations (see Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999)). Thus, recitation of statements describing the claimed product as a product which is intended to be used to diagnose or aid in the diagnosis of cervical cancer are not given patentable weight and are not limitations to the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4, 5, 17, 60, 63, 64, 68, 69, 71, and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lloyd et al (J Clin Pathol, February 1984, 37:131-135) in view of Shinohara et al (Gynecologic Oncology, September 2001, 82:450-455).

The claims are drawn to methods of diagnosing and classifying the grade of cervical cancer comprising detecting the expression level of transferrin receptor and the level of beta-catenin in the cytoplasm and/or nucleus. The claims are further drawn to kits for performing said methods.

Lloyd et al teaches a method of diagnosing or aiding in the diagnosis of cervical cancer and detecting immortalization of cervical cancer cells in a female comprising analyzing the expression level of transferrin receptor wherein increased expression of transferrin receptor relative to an appropriate control indicates that a female has or is at increased risk of having cervical cancer (right column of page 132, in particular). Lloyd et al further teaches a method of classifying the grade of a cervical lesion comprising determining the expression of transferrin receptor and comparing said expression relative to a reference panel comprising a constituent panel developed using cervical cancer, high grade cervical lesion, low grade cervical lesion, and a control group and classifying a cervical lesion by said comparison (see right column of page 132 and Table 1, in particular). Lloyd et al further teaches a kit for diagnosing and aiding in the diagnosis of cervical cancer comprising antibodies that specifically bind transferrin receptor and appropriate control reagents (left column of page 132, in particular).

Lloyd et al does not specifically teach a method of diagnosing or aiding in the diagnosis of cervical cancer and detecting immortalization of cervical cancer cells in a female comprising analyzing the level of beta-catenin in the cytoplasm and/or nucleus and increased level of beta-catenin in the cytoplasm and/or nucleus relative to an appropriate control indicates that a female has cervical cancer or is at the risk of

developing cervical cancer. Further, Lloyd et al does not specifically teach a method of classifying the grade of a cervical lesion comprising determining the level of beta-catenin in the cytoplasm and/or nucleus and comparing said level to a reference panel comprising a constituent panel developed using cervical cancer, high grade cervical lesion, low grade cervical lesion, and a control group and classifying a cervical lesion by said comparison. Further, Lloyd et al does not specifically teach a kit for diagnosing and aiding in the diagnosis of cervical cancer comprising antibodies that specifically bind beta-catenin. However, these deficiencies are made up in the teachings of Shinohara et al.

Shinohara et al teaches a method of diagnosing or aiding in the diagnosis of cervical cancer and detecting immortalization of cervical cancer cells in a female comprising analyzing the level of beta-catenin in the cytoplasm and/or nucleus and increased level of beta-catenin in the cytoplasm and/or nucleus relative to an appropriate control indicates that a female has cervical cancer or is at the risk of developing cervical cancer (Table 1, in particular). Shinohara et al further teaches a method of classifying the grade of a cervical lesion comprising determining the level of beta-catenin in the cytoplasm and/or nucleus and comparing said level to a reference panel comprising a constituent panel developed using cervical cancer, high grade cervical lesion, low grade cervical lesion, and a control group and classifying a cervical lesion by said comparison (Table 1, in particular). Shinohara et al further teaches a kit for diagnosing and aiding in the diagnosis of cervical cancer comprising antibodies that specifically bind beta-catenin and appropriate control reagents (page 451, in particular).

One of ordinary skill in the art at the time the invention was made would have been motivated to combine the methods of detecting, diagnosing, and classifying cervical cancer taught by Lloyd et al with the methods of detecting, diagnosing, and classifying cervical cancer taught by Shinohara et al because Lloyd et al indicates that a second marker for cervical cancer malignancy be used to better classify said cervical cancer (see paragraph bridging the columns on page 134, in particular) and Shinohara et al clearly teaches a second marker for classifying and diagnosing cervical cancer (Table 1, in particular). Further, as compared to using just one marker, one of skill in the art would recognize that methods using multiple markers to detect, diagnose, and classify cervical cancer would provide a more accurate detection, diagnosis, and classification. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for performing the methods of detecting, diagnosing, and classifying cervical cancer taught by Lloyd et al with the methods of detecting, diagnosing, and classifying cervical cancer taught by Shinohara et al because Lloyd et al and Shinohara et al teach how to perform said methods (see page 132 of Lloyd et al and page 451 of Shinohara et al, in particular). Further, in order to perform said combined methods in a streamlined manner, one of skill in the art would be motivated to combine the kit taught by Lloyd et al with the kit taught by Shinohara et al. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results.

Summary

No claim is allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SEA
/Misook Yu/

Primary Examiner, Art Unit 1642